REMARKS

In response to the Final Office Action mailed June 26, 2009, claims 1, 5, 21, and 24-26 have been amended. Accordingly, claims 1, 5, 7, 8, 21-31, and 74-76 remain pending. Support for the amendments may be found throughout the original disclosure, for example, in the specification, e.g., in paragraphs [0050], [0119], and [0127]-[0129], and in the drawings, e.g., in FIGS. 1A-1C and 18-29. No new matter has been introduced.

In the Final Office Action, claims 21-26 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,002,563 ("the Pyka et al. reference"), claims 1, 27, 28, 74, and 75 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Pyka et al. reference in view of U.S. Patent No. 2,199,025 ("the Conn reference"), claims 5, 7, 8, and 76 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Pyka et al. reference in view of U.S. Patent No. 4,549,545 ("the Levy reference"), and claims 29-31 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Pyka et al. reference. Because none the cited references, either alone or in combination, fail to discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning to the Pyka et al. reference, shape memory alloy sutures are disclosed for suturing wounds in tissue. Col. 1, lines 5-6, col. 3, lines 3-5. For example, the suture 10 shown in FIGS. 1-4B includes a wire member 18 formed into a loop 12 with a needle 14 attached to or formed on one end 16. Col. 4, lines 59-66. FIG. 1 shows the undeformed loop configuration of the suture 10, which can be manually straightened such that, when the deforming force is removed, the suture 10 automatically returns to the loop configuration. Col. 5, lines 23-30.

During use, the suture 10 is placed under sufficient stress to deform it into a deformed state that is straight enough for it to be threaded through tissue, and, as the stress is removed, the suture 10 forms the loop 12 by springing back due to its pseudoelastic nature. Col. 5, lines 33-42.

Thus, the Pyka et al. reference teaches nothing about a fastener that includes a leg that is formed from material that is ***plastically deformed when the leg is bent***. In fact, the Pyka et al. reference expressly teaches against such fasteners. See col. 3, lines 31-37, which discusses conventional sutures and staples, and alleges that such devices requiring tying off or cause undesired shear forces to tissue. Unlike the shape memory sutures of the Pyka et al. references, staples are plastically deformed to bend ends of the fastener to secure the fastener in place. The Pyka et al. sutures use shape memory material to allow the suture to automatically loop or curve to secure the sutures across a wound in tissue to close the wound and do not involve plastic deformation.

In addition, the Pyka et al. reference fails to disclose, teach, or suggest fasteners that are long enough to extend out of a patient when a base of the fastener is in anchoring position within the patient's body. Such extremely long fasteners may be used to guide other devices, such as heart valve prostheses, into position in a patient's body before being cut and bent. See, e.g., paragraphs [0111], [0118], FIGS. 6-9 of the present application. The Pyka et al. reference does not teach or suggest anything about devices capable of being such a guide, but merely discloses shape memory sutures that automatically loop when released to close wounds in tissue. Such sutures would be completely incapable of being used to guide a prosthesis into a patient's body. In particular, if the sutures were not held under constant tension, the sutures would automatically

begin to loop, which would make it difficult if not impossible to guide a prosthesis along such a suture.

Turning to the present claims, claim 1 recites a fastener for use in surgery comprising a body having a base and a leg extending from said base; said body having a width dimension; said leg having an initial pointed end, an unformed length dimension measured from said base to said initial pointed end that is long enough to extend out of a patient when the base is in anchoring position within the patient's body, the leg configured to be cut between the base and the initial pointed end to a formed length dimension measured between said base and a new end, with the new end located between the initial pointed end and said base such that the unformed length is greater than the formed length, the leg formed from material that is plastically deformed when the leg is bent to force the new end back towards the base to secure the fastener to tissue; and a pledget on the body adjacent the base.

As explained above, the Pyka et al. reference fails to disclose, teach, or suggest a fastener having a leg formed from material that is ***plastically deformed when the leg is bent*** to force the new end back towards the base to secure the fastener to tissue, as claimed. Instead, the Pyka et al. sutures are formed from shape memory material such that, when the sutures are released or cut, the sutures automatically curve or loop. Such shape memory materials would be incapable of being plastically deformed to force ends of the sutures because of the pseudoelastic/ superelastic properties of the materials, as would be appreciated by a person of ordinary skill in the art. Instead, because the shape of the Pyka et al. sutures is set into the suture material, if the ends were bent after being cut, they would simply spring back to their original shape when

released and not remain bent. Further, the sutures would be incapable of being cut at any desired location along the length of the sutures without the cut ends simply springing back to their original shape.

Finally, the other cited references fail to provide any additional teaching or suggestion that may be properly combined with the Pyka et al. reference. Accordingly, for these reasons, claim 1 is neither anticipated by nor otherwise obvious over the Pyka et al. reference, either alone or in combination with the other cited references.

For similar reasons, claim 5 and its dependent claims are also not anticipated by or obvious over the cited references. Claim 5 also recites a fastener comprising a U-shaped body having a base and two legs extending from the base, the body formed from material that is plastically deformed when the leg is bent to force cut ends of the legs back towards the base to secure the fastener to tissue, similar to claim 1.

In addition, claim 5 also recites that each leg has a pointed end and a length dimension measured from the base to the pointed end thereof that is ***long enough to extend out of a patient when the base is in anchoring position within the patient's body***. As explained above, the Pyka et al. reference fails to teach or suggest a leg having such a length. This distinction is further reinforced in claim 74, which recites that the length dimension measured from the base to the pointed end is between ten and twenty inches. Instead, the Pyka et al. reference discloses sutures including a loop that is sufficiently small to allow the suture to pull tissue closed over a wound. Such a suture would not be sufficiently long to extend out of a patient, and would clearly be incapable of guiding a prosthesis or other device along the suture.

Therefore, for these reasons, claim 5 and its dependent claims are also neither anticipated by nor otherwise obvious over the Pyka et al. reference, alone or in combination with the other cited references.

Turning to claim 21, a method is recited of placing a fastener in a patient during surgery that includes providing a fastener for use in surgery having a body having a base and a leg extending from said base, said leg having a pointed end and a length measured from said base, said length being indeterminate; locating the fastener inside a patient on one side of a tissue being operated on; driving a pointed end of the fastener through the tissue; grasping the leg after the leg has penetrated the tissue; tensioning the leg and moving the base of the fastener against the tissue; immobilizing the leg on the other side of the tissue; engaging the end of the immobilized leg; and bending the leg to plastically deform the leg and force the end back towards the base of the fastener.

As explained above, neither the Pyka et al. reference nor the other cited references discloses, teaches, or suggests bending a leg of a fastener ***to plastically deform the leg*** and force the end back towards a base of the fastener. Accordingly, claim 21 and its dependent claims are neither anticipated by nor otherwise obvious over the Pyka et al. reference.

For similar reasons, claims 24, 25, 26, and their dependent claims are also neither anticipated by nor otherwise obvious over the cited references. Claims 24 and 26 recite bending the leg to plastically deform the leg and force the end back towards the base of the fastener, while claim 25 recites bending the new end to plastically deform the leg and force the new end back towards the base of the fastener. Such bending causing plastic deformation is not disclosed,

taught, or suggested by the Pyka et al. reference, either alone or in combination with the other cited references. Further, given that the Pyka et al. reference teaches against forcibly bending ends of a fastener and instead discloses using shape memory material, such bending as recited in the present claims would not be obvious even if disclosed in another reference, since it could not be properly combined with the Pyka et al. reference.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,
VISTA IP LAW GROUP LLP

Date: August 26, 2009 By /william a. english/
William A. English
Reg. No. 42,515
Attorneys for Applicants

2040 Main Street, 9th Floor
Irvine, CA 92614
Telephone: (562) 665-3953
Facsimile: (949) 625-8955